IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JOHN BARTIS, Plaintiff, v. BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET MANUFACTURING CORP. Defendants.	Cause No.: 4:13-cv-00657 **JURY TRIAL DEMANDED**

COMPLAINT

SUBJECT MATTER JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff John Bartis is a citizen of Dallas, Texas, which is different from the states where Defendants are all incorporated and have their principal places of business.

2. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because a substantial part of the events giving rise to the claim occurred in this district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c), as Plaintiff received the hip systems in this district and Defendants conducted continuous, systematic, and substantial business in this district.

NATURE OF THE CASE

3. This is an action for product liability on behalf of Plaintiff John Bartis against Defendants who were responsible for the defective hip systems implanted in Plaintiff John

Bartis, which has caused significant pain and elevated metal levels, resulting in multiple revision surgeries.

PARTY DEFENDANTS

4. On information and belief, Defendant Biomet, Inc. is a corporation organized and existing under the laws of the State of Indiana with its primary place of business in Warsaw, Indiana. Biomet, Inc. designed, manufactured, marketed, promoted, and sold the M^2a-Magnum™ Hip Implant System that is the subject of this lawsuit. Defendant Biomet, Inc. is and was at all times relevant herein doing business in and/or having directed its activities at the State of Missouri, and regularly conducted business in the State of Missouri and throughout the United States.

5. On information and belief, Defendant Biomet Orthopedics, LLC is, and at all times relevant hereto was, a wholly owned subsidiary of Defendant Biomet U.S. Reconstruction, LLC and is a limited liability corporation organized and existing under the laws of the State of Indiana with its primary place of business in Warsaw, Indiana. Defendant Biomet Orthopedics, LLC designed, manufactured, marketed, promoted, and sold the M^2a-Magnum™ Hip Implant System that is the subject of this lawsuit. Defendant Biomet Orthopedics, LLC is and was at all times relevant herein doing business in and/or having directed its activities at the State of Missouri, and regularly conducted business in the State of Missouri and throughout the United States.

6. On information and belief, Defendant Biomet U.S. Reconstruction, LLC is, and at times relevant to this Complaint was, a wholly owned subsidiary of Defendant Biomet, Inc., and an Indiana Corporation with its principal places of business in Warsaw, Indiana. Biomet US Reconstruction, LLC, designed, manufactured, marketed, promoted, and sold the M^2a-

Magnum™ Hip Implant System that is the subject of this lawsuit and was at all times relevant herein doing business in and/or having directed its activities at the State of Missouri, and regularly conducted business in the State of Missouri and throughout the United States.

7. On information and belief, Defendant Biomet Manufacturing Corp. is, and was at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant, Biomet, Inc., and an Indiana Corporation with its principal place of business in Warsaw, Indiana. Defendant Biomet Manufacturing Corp. designed, manufactured, marketed, promoted, and sold the M^2a-Magnum™ Hip Implant System that is the subject of the lawsuit and was at all times relevant herein doing business in and/or having directed its activities at the State of Missouri, and regularly conducted business in the State of Missouri and throughout the United States.

8. Defendants, Biomet, Inc., Biomet Orthopedics, LLC, Biomet US Reconstruction, LLC and Biomet Manufacturing Corp. are collectively referred to herein as "Biomet" or "Defendants."

9. At all times mentioned, Defendants were the representatives, agents, employees, joint ventures, or alter egos of each of the other entities and in doing the things alleged herein were acting within the scope of their authority as such. Specifically, each Defendant was but an instrumentality or conduit of the others in the prosecution of a single venture, namely the design, promotion, and sale of the M^2a-Magnum™ Hip Implant System. Therefore, it would be inequitable for any Defendant to escape liability of an obligation incurred as much for that Defendant's benefit as for the others.

10. At all times relevant herein, Defendants transacted, solicited, and conducted business in the State of Missouri, and in particular this district, and derived substantial revenue from such business.

11. Upon information and belief, at all relevant times, Defendants committed tortuous act(s) within the State of Missouri, out of which act(s) these causes of action arise.

FACTUAL BACKGROUND

A. The M^{2}a-Magnum™ Hip Implant System Is Defective and Was Not Adequately Tested

12. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

13. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

14. While most hip replacements use a polyethylene plastic acetabular liner, Biomet's M^{2}a-Magnum™ Hip Implant System has a critical difference – it is a monoblock system which does not have an acetabular liner. Instead, the M^{2}a-Magnum™ Hip Implant System forces metal to rub against metal with the full weight and pressure of the human body. Because of Biomet's defective design for the M^{2}a-Magnum™ Hip Implant System, hundreds of patients, including Plaintiff, have been forced to undergo surgeries to replace the failed hip implant.

15. The M^{2}a-Magnum™ Hip Implant System suffers from a design or manufacturing defect that causes excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

16. The design of the M^{2}a-Magnum™ Hip Implant System was not sufficiently tested by Biomet.

17. On numerous occasions, Biomet met with orthopedic surgeons throughout the United States, and other cities to promote the M^{2}a-Magnum™ Hip Implant System. At some or all of these meetings, a representative or representatives of Biomet was present. During these meetings, Biomet assured the orthopedic surgeons that the M^{2}a-Magnum™ Hip Implant System was safe, was the best product on the market, had an excellent track record, and a low and acceptable failure rate. Biomet continued to "defend" the M^{2}a-Magnum™ Hip Implant System even after they became aware of numerous and serious complications with the M^{2}a-Magnum™ Hip Implant System. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

B. Biomet Sold The M^{2}a-Magnum™ Hip Implant to Plaintiff After It Knew The M^{2}a-Magnum™ Hip Implant Was Defective, Had Injured Others, And Would Injure Plaintiff

18. It wasn't long after Biomet launched the M^{2}a-Magnum™ Hip Implant System that reports of failures began flooding into Biomet.

19. Biomet would go on to receive hundreds of similar complaints reporting that the M^{2}a-Magnum™ Hip Implant System had failed and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, more than 350 reports of adverse events associated with the M^{2}a-Magnum™ Hip Implant System have been filed with the FDA.

20. By the time Biomet sold the M^{2}a-Magnum™ Hip Implant System to Plaintiff, numerous reports had been filed with the FDDA reporting an adverse event associated with the M^{2}a-Magnum™ Hip Implant System. Consequently, Biomet was fully aware that the M^{2}a-Magnum™ Hip Implant System was defective and that dozens of patients had already been injured by that defect. Based on this information, Biomet should have recalled the M^{2}a-Magnum™ Hip Implant System before it was sold to Plaintiff. At a minimum, Biomet should have stopped selling the defective implant when it became aware that it had catastrophically failed in several patients.

21. Despite its knowledge that the M^{2}a-Magnum™ Hip Implant System has a defect and that it has failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, Biomet continues to sell the defective M^{2}a-Magnum™ Hip Implant System. In doing so, Biomet actively concealed the known defect from doctors and patients, including Plaintiff and Plaintiff's doctor, and misrepresented that the M^{2}a-Magnum™ Hip Implant System was/is a safe and effective medical device.

22. As numerous failures of the M^{2}a-Magnum™ Hip Implant System were reported to Biomet, it continued to actively promote, market, and defend the defective products. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants and specifically, the M^{2}a-Magnum™ Hip Implant System. These brochures were

given to doctors around the world, including Plaintiff's orthopedic surgeon, to encourage them to use the M^{2}a-Magnum™ Hip Implant System.

23. Despite its knowledge that the M^{2}a-Magnum™ Hip Implant System was defective, Biomet also made several false representations about specific design elements of the M^{2}a-Magnum™ Hip Implant System that they claimed made it superior to other more safe hip implants on the market. For example, Biomet said:

- "The M^{2}a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo."
- "Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

24. Biomet's reason to conceal the defect in its M^{2}a-Magnum™ Hip Implant System is clear. Hip implant sales are critically important to Biomet, and the M^{2}a-Magnum™ is one of its most profitable products. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors, and they ultimately were purchased by a private equity firm in 2007 for $10 billion. Biomet was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Biomet decided that it would continue to promote, market, and sell the M^{2}a-Magnum™ Hip Implant System despite the fact that it knew the product was defective. To this day, Biomet continues to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Plaintiff's M²a-Magnum™ Hip Implant System Was Defective and Failed, Forcing Plaintiff to Undergo an Additional Painful and Risky Surgery

25. On October 18, 2007, Plaintiff underwent a surgical procedure to implant the M²a-Magnum™ Hip Implant System in Plaintiff's right hip by Dr. Joseph Williams at Missouri Baptist Medical Center in St. Louis, Missouri.

26. On November 29, 2007, Plaintiff underwent a surgical procedure to implant the M²a-Magnum™ Hip Implant System in Plaintiff's left hip by Dr. Joseph Williams at Missouri Baptist Medical Center in St. Louis, Missouri. By this time, Biomet knew that the product was defective, but Biomet refused to disclose that information to Plaintiff, Plaintiff's physicians, or the public. Instead, Biomet misrepresented to Plaintiff and Plaintiff's orthopedic surgeon that the M²a-Magnum™ Hip Implant System was safe and effective. In reliance on these representations, Plaintiff's orthopedic surgeon made the decision to use the M²a-Magnum™ Hip Implant System. If it were not for the misrepresentations made by Biomet, Plaintiff's orthopedic surgeon would not have used the M²a-Magnum™ Hip Implant System in Plaintiff's hip replacement surgery.

27. As a result of the defective design, manufacture, and composition of the M²a-Magnum™ Hip Implant System, and its accompanying warnings and instructions (or lack thereof), Plaintiff's hip implant failed, causing Plaintiff severe pain, elevated metal levels, and metallosis resulting in multiple revision surgeries.

28. Plaintiff has not yet scheduled an explantation of the M²a-Magnum™ Hip Implant System from Plaintiff's right hip.

29. On April 9, 2008, Plaintiff underwent a complex, risky and painful surgery (known as a "revision surgery") to remove the failed M²a-Magnum™ Hip Implant System from Plaintiff's left hip.

30. Subsequently, on June 3, 2011 and June 20, 2011, Plaintiff underwent additional revision surgeries on the left hip. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

31. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, et al. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20-26.)

32. As a direct and proximate result of the failure of her defective M^2a-Magnum™ Hip Implant System and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000.00 jurisdictional amount of this Court.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

33. The running of any statute of limitation has been tolled by reason of Defendants' conduct. Defendants, through their affirmative misrepresentations and omissions, actively

concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with Biomet.

34. As a result of Defendants' actions, Plaintiff and Plaintiff's prescribing physicians were unaware and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein, and that those risks were the direct and proximate result of the Defendants' acts and omissions.

35. Furthermore, Defendants are stopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of the M^{2}a-Magnum™ Hip Implant System. Defendants were under duty to disclose the true character, quality and nature of the M^{2}a-Magnum™ Hip Implant System because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers and/or to Plaintiff's health facilities.

36. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose marketing and promoting a profitable medical device, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of health-related risks, and were forced to rely on the Defendants' representations.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
(Against All Defendants)

37. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

38. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices, including the M^{2}a-Magnum™ Hip Implant System.

39. The M^{2}a-Magnum™ Hip Implant System manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

40. As a direct and proximate result of the Plaintiff's use of Defendants' M^{2}a-Magnum™ Hip Implant System as manufactured, designed, sold, supplied, and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

41. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

42. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT
(Against All Defendants)

43. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

44. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the M^2a-Magnum™ Hip Implant System.

45. The M^2a-Magnum™ Hip Implant System manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

46. The foreseeable risks associated with the design or formulation of the M^2a-Magnum™ Hip Implant System include, but are not limited to, the fact that the design or formulation of the M^2a-Magnum™ Hip Implant System is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

47. As a direct and proximate result of the Plaintiff's use of the M^2a-Magnum™ Hip Implant System as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or its failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

48. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

49. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS
(Against All Defendants)

50. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

51. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices, including the M^{2}a-Magnum™ Hip Implant System.

52. The M^{2}a-Magnum™ Hip Implant System manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not confirm to representations made by Defendants concerning the product and/or with applicable federal requirements.

53. Defendants made representations to consumers regarding the character or quality of the M^{2}a-Magnum™ Hip Implant System, including but not limited to, statements that the M^{2}a-Magnum™ Hip Implant System was a safe and durable hip replacement system. They further asserted that the "Biomet metal-on-metal (MoM) M^{2}a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo. Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited form metal-on-metal implants."

54. The Plaintiff and/or Plaintiff's physicians justifiably relied upon Defendants' representations regarding the M^{2}a-Magnum™ Hip Implant System when they selected these Biomet orthopedic products to be used in surgery.

55. As a direct and proximate result of the Plaintiff's use of the M^{2}a-Magnum™ Hip Implant System, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the M^{2}a-Magnum™ Hip Implant System and/or failure to comply with federal

requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

56. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

57. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against All Defendants)

58. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

59. The M^2a-Magnum™ Hip Implant System was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the M^2a-Magnum™ Hip Implant System, including but not limited to, the risks of developing serious and dangerous side effects, component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the M^2a-Magnum™ Hip Implant System, as well as other severe and permanent health consequences notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

60. At the time of the Plaintiff's receipt and/or use of the M^{2}a-Magnum™ Hip Implant System, the M^{2}a-Magnum™ Hip Implant System was being used for the purposes and in a manner normally intended, namely for hip arthroplasty.

61. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

62. Defendants, as manufactures and/or distributors of the M^{2}a-Magnum™ Hip Implant System, are held to the level of knowledge of an expert in the field.

63. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous.

64. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks, subjecting Plaintiff to risks that exceeded the benefits of the M^{2}a-Magnum™ Hip Implant System, including but not limited to, component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity, irritation and discomfort, as well as the need for additional procedures to remove and replace the M^{2}a-Magnum™ Hip Implant System, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries of side effects over other hip arthroplasty devices.

65. Plaintiff, individually and through Plaintiff's physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants.

66. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the M^{2}a-Magnum™ Hip Implant System.

67. Had Plaintiff received adequate warnings regarding the risks of the M^{2}a-Magnum™ Hip Implant System, Plaintiff would not have used it.

68. As a direct and proximate result of the Plaintiff's use of the M^{2}a-Magnum™ Hip Implant System, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the M^{2}a-Magnum™ Hip Implant System, and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

69. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

70. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
NEGLIGENCE
(Against All Defendants)

71. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

72. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the M^{2}a-Magnum™ Hip Implant System into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

73. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the M^{2}a-Magnum™ Hip Implant System into interstate commerce in that

Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

74. Despite the fact that Defendants knew or should have known that the M^2a-Magnum™ Hip Implant System posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the M^2a-Magnum™ Hip Implant System for use by consumers and/or continued to fail to comply with federal requirements.

75. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

76. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

77. Defendants' conduct as described above, including but not limited to, its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M^2a-Magnum™ Hip Implant System when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

78. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

79. Defendants expressly warranted that the M^{2}a-Magnum™ Hip Implant System was a safe and effective orthopedic device for those patients requiring a hip replacement.

80. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

81. Defendants' conduct as described above, including but not limited to, its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M^{2}a-Magnum™ Hip Implant System when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

82. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

83. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

84. At the time Defendants designed, manufactured, marketed, sold, and distributed the M^{2}a-Magnum™ Hip Implant System for use by the Plaintiff, Defendants knew of the use for which the M^{2}a-Magnum™ Hip Implant System was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

85. The Plaintiff and/or his physicians reasonably relied upon the skill and judgment of Defendants as to whether the M^{2}a-Magnum™ Hip Implant System was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

86. Contrary to such implied warranty, Biomet's M^{2}a-Magnum™ Hip Implant System was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

87. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

88. Defendants' conduct as described above, including but not limited to, its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M^{2}a-Magnum™ Hip Implant System when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

89. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble

and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATIONS
(Against All Defendants)

90. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

91. In the exercise of reasonable care, Defendants should have known that its M^2a-Magnum™ Hip Implant System failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendants negligently misrepresented to the Plaintiff and/or Plaintiff's physicians that its device was safe and met all applicable design and manufacturing requirements.

92. The Plaintiff and/or Plaintiff's physicians reasonably relied to their detriment upon Defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products. The Plaintiff and/or Plaintiff's physicians reasonably relied upon Defendants' representations that the M^2a-Magnum™ Hip Implant System was safe for use.

93. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M^2a-Magnum™ Hip Implant System, Plaintiff used Defendants M^2a-Magnum™ Hip Implant System and Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

94. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

95. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper

NINTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION
(Against All Defendants)

96. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and alleges as follows:

97. Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff, and/or the FDA, and the public in general, that the subject product had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

98. The representations made by the Defendants were, in fact, false.

99. When said representations were made by the Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

100. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including but not limited to claims that the M^2a-Magnum™ Hip Implant System was a safe and durable hip replacement system.

101. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the

subject product for hip arthroplasty treatment, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

102. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff was treated with the M^{2}a-Magnum™ Hip Implant System, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

103. In reliance upon said representations, Plaintiff was induced to, and did use the subject product, thereby sustaining severe and permanent personal injuries, including but not limited to, significant pain, discomfort, elevated metal levels resulting in revision surgery, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

104. Defendants knew and were aware or should have been aware that the M^{2}a-Magnum™ Hip Implant System had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

105. Defendants knew or should have known that the M^{2}a-Magnum™ Hip Implant System had a potential to, could and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or downplayed warnings.

106. Defendants brought the subject product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

107. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M^{2}a-Magnum™ Hip Implant System, the Plaintiff used Defendants' M^{2}a-Magnum™ Hip

Implant System and the Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

108. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

109. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT
(Against All Defendants)

110. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and alleges as follows:

111. At all times during the course of dealing between the Defendants and Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of the subject product for its intended use.

112. Defendants knew or were reckless in not knowing that its representations were false.

113. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

a. the subject product was not as safe as other similar drugs and medications indicated for hip arthroplasty;

b. That the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the M^{2}a-Magnum™ Hip Implant System, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

c. that the subject product was manufactured negligently;

d. that the subject product was manufactured defectively;

e. that the subject product was manufactured improperly;

f. that the subject product was designed negligently;

g. that the subject product was designed defectively; and

h. that the subject product was designed improperly.

114. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to, the risk of developing elevated metal ion levels, device failure resulting in the need for revision surgery associated with the use of the M^{2}a-Magnum™ Hip Implant System.

115. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the M^{2}a-Magnum™ Hip Implant System, including the Plaintiff, in particular.

116. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the M^{2}a-Magnum™ Hip Implant System was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the M^{2}a-Magnum™ Hip Implant System, and to cause them to purchase, prescribe, dispense and/or use the subject product.

117. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

118. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

119. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M^{2}a-Magnum™ Hip Implant System, Plaintiff used Defendants' M^{2}a-Magnum™ Hip Implant System and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

120. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

121. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION
PUNITIVE DAMAGES
(Against All Defendants)

122. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

123. At all times material hereto, the Defendants knew or should have known that their M^2a-Magnum™ Hip Implant System was inherently more dangerous with respect to the risk of significant pain, irritation, discomfort and need for additional surgeries than the alternative hip arthroplasty systems on the market.

124. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

125. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

126. At all times material hereto, the Defendants knew and recklessly disregarded the fact that that M^2a-Magnum™ Hip Implant System was subject to an increased risk of causing significant pain, irritation, discomfort and need for additional surgeries in persons implanted with the device with far greater frequency than safer alternative hip arthroplasty systems.

127. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

128. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of

the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

129. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and Plaintiff's surgeon of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

130. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

131. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

132. The Plaintiff seeks actual punitive damages for the Defendants as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff John Bartis, healthcare costs, medical monitoring, together with the interest and costs as provided by the law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the

safety and welfare of the general public and the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff's attorneys' fees;

4. Awarding Plaintiff the costs of the proceedings; and

5. Such other and further relief as this Court deems just and proper.

Dated: _____, 2013

Respectfully submitted,

ONDER, SHELTON, O'LEARY & PETERSON LLC

By: _____

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